CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED ADOPTION OF INTELLECTUAL PROPERTY REGULATIONS FOR NON-PROFIT AND FOR-PROFIT GRANTEES

HEARING DATE: None scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: Intellectual Property and Revenue Sharing Requirements for Non- and For-Profit Organizations

SECTIONS AFFECTED: The proposed regulations adopt Chapter 6 and sections 1004600, 100601, 100602, 100603, 100604, 100605, 100606, 100607, 100608, 100609, 100610 and 100611 of Title 17 of the California Code of Regulations. The proposed action deletes sections 100300-100306, 100308-100310, and 100400 – 100410.

SPECIFIC PURPOSE OF REPEAL: The repeal of Title 17, sections 100300-100306, 100308-100310, and 100400 – 100410, is to consolidate their provisions in one unified policy as embodied in the regulations proposed for adoption described below (sections 100600 – 100611).

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:

SECTION 100600 – INTELLECTUAL PROPERTY AND REVENUE SHARING REQUIREMENTS FOR NON-PROFIT AND FOR-PROFIT GRANTEES - SCOPE:

Purpose:

Section 100600 establishes the scope of the regulations comprising Chapter 6. The regulations in this chapter apply to all CIRM grant awards issued on or after the effective date of the regulations to both non-profit and for-profit grantees. Amended regulations become applicable to currently active grants on the start date of the next non-competitive renewal period, except for amendments to sections 100606, 100607 and 100608, which shall only apply to grants awarded after adoption of the new or amended regulations. The regulation indicates revisions to CIRM regulations will be posted on the CIRM website.

Rationale: This section is necessary to define the circumstances and extent to which this chapter is to be applied. Because grants can exist over multiple numbers of years, it is necessary to indicate how revised grant regulations are to be applied to existing grants. The regulation addresses two types of grants – those which are "currently active" and those which are not. The regulation also informs recipients that the CIRM website will contain updates of regulations, which is aimed to inform recipients that the website can be relied upon to track potential amendments to these regulations and policies.

SECTION 100601 – INTELLECTUAL PROPERTY REGULATIONS – DEFINITIONS:

Purpose:

The following definitions shall apply to language contained in Sections 100400 through 100410 of these regulations.

(a) "Authorized Organizational Official." The individual, named by the applicant organization, who is authorized to execute agreements that legally bind the Grantee to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Grant applications or Grant awards.

(b) "CIRM-Funded Invention." An Invention, whether patentable or not, arising from CIRM-Funded Research, conceived and/or first reduced to practice during the performance of a Currently Active Grant by a Grantee and/or its Collaborator(s) or within two years of the close of the Grant.

(c) "CIRM-Funded Research." All aspects of work conducted on a Currently Active Grant by a Grantee [and/or] its Collaborators(s) that is paid for, in whole or in part, with CIRM funds.

(d) "CIRM-Funded Technology." Data, materials, research results or know-how whether patentable or not, that is conceived and/or first reduced to practice in the performance of a Currently Active Grant (or within two years of the close of the Grant) and paid for in whole or in part with CIRM-funds.

(e) "Collaborator." Any person or entity, other than a Grantee and Grantee Personnel, who conducts research and/or related work described in a Grant application.

(f) "Currently Active Grant." A Grant: (i) that is still in the Project Period; (ii) that is outside the Project Period but CIRM Grant funds are still being spent on the project; or (iii) for which the repayment of CIRM grant funds remains unsatisfied.

(g) "Data." Recorded information, regardless of form or the media on which it may be recorded, including, but not limited to, recorded information of a scientific or technical nature, but not any of the following: financial, administrative, management data, other information incidental to contract administration, preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. "Data" excludes physical objects (e.g., laboratory samples).

(h) "Drug." (1) An article recognized in the official United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure,

mitigation, treatment, or prevention of disease in man or other animals; or, (3) an article intended for use as a component of any article specified in subdivision (1) or (2). This term includes therapeutic products such as blood, blood products, cells, and cell therapies.

(i) "Exclusive License." An agreement for CIRM-Funded Technology or a CIRM-Funded Invention that transfers, or that conveys to the licensee, the exclusive exercise of, the right to make, use, sell, offer for sale and/or import in one or more fields of use or territories.

(j) "Exclusive Licensee." Any individual or entity receiving all rights to make, use, sell, offer for sale and/or import in one or more fields of use or territories a CIRM-Funded Technology or a CIRM-Funded Invention, whether by assignment, license, or other mechanism.

(k) "For-Profit Organization." A legal entity that is organized for the profit or benefit of its shareholders or owners.

(l) "Grant." CIRM funding, other than a loan, in the form of a payment to conduct research and/or related work.

(m) "Grantee." The Non-Profit Organization or For-Profit Organization awarded a Grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The Grantee is the entire legal entity, including Affiliates, even if only a particular division is designated in the Notice of Grant Award ("NGA"). An entity is an Affiliate of a Grantee if both entities share substantial common direction or control (either directly or indirectly), or if either entity owns (directly or through one or more entities) at least a 25% capital or profits interest in the other. All University of California Grantee campuses shall be considered as separate and individual Grantees.

(n) "Grantee Personnel." Grantee's Principal Investigator(s) and Grantee employees, students and contractors working under the direction of the Principal Investigator under the Grant.

(o) "Invention." A discovery that is conceived and/or reduced to practice, whether patentable or not.

(p) "Inventor." A person who is an inventor under a governing jurisdiction's patent law.

(q) "License Agreement." An agreement by which an owner of a CIRM-Funded Invention or CIRM-Funded Technology conveys the right to make, use, develop, sell, offer to sell, and/or import a CIRM-Funded Invention or CIRM-Funded Technology in exchange for consideration.

(r) "Licensing Activities." Efforts of an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology to negotiate, execute or enforce a License Agreement.

(s) "Licensing Revenue." The consideration rendered to an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology pursuant to a License Agreement. In the case of Non-Profit Grantee only, Licensing Revenue does not include amounts due to the Inventor pursuant to existing institutional policies. For all owners and licensees of a CIRM-Funded Invention or CIRM-Funded Technology, a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such Invention and Technology may be deducted from Licensing Revenue except to the extent that such expenses are recovered from a third party as provided in Section 100405(d) or otherwise.

(t) "Material Transfer Agreement ("MTA")." An agreement that governs the transfer of tangible research material between a Grantee and/or its collaborator and an individual or entity ("Recipient") and defines the rights of the Grantee and the rights and limitations of the Recipient with respect to the materials and any derivatives.

(u) "Net Commercial Revenue." Income from the sale or transfer, but not licensing or assignment, of a Drug or product(s) resulting in whole or in part from CIRM-Funded Research. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-Funded Research):
(1) import, export, excise and sales taxes, and customs duties;
(2) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises;
(3) credit for returns, allowances or trades; and
(4) pre-commercial revenues received in connection with research and development and/or clinical activities.

(v) "Non-Exclusive License." An agreement that transfers, or that conveys to more than one viable licensee, the right to make, use, sell, offer for sale and/or import in a specified field of use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, including co-exclusive or semi-exclusive arrangements.

(w) "Non-Exclusive Licensee." Any individual or entity that shares with another individual or entity the right to make, use, sell, offer for sale and/or import in as specific field of use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, through a Non-Exclusive License.

(x) "Non-Profit Organization." A university or other institution of higher education or another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)); or any other non-profit scientific or educational organization qualified under a state non-profit organization statute whose organizational charter provides that (A) the organization is not organized or operated for the private gain of any person, (B) no part of the organization's net income or assets shall

inure to the benefit of any person, and (C) the organization's net assets upon dissolution shall be distributed to a non-profit fund, foundation or corporation which is organized and operated exclusively for charitable purposes.

(y) "Notice of Grant Award ("NGA")." The CIRM document that notifies the Grantee that an award has been made, contains or references all terms and conditions of the award, and documents the obligations of the Grantee.

(z) "Principal Investigator." The Principal Investigator ("PI") is one or more individuals designated by the Grantee to direct CIRM-Funded Research and who is accountable to the Grantee and to CIRM for the proper conduct of that research.

(aa) "Project Period." The amount of time over which CIRM funds research through a Grant.

(bb) "Public Funds." Funds belonging to the State of California or of any county, city, city and county, or other municipal corporation or subdivision thereof, or any public agency therein.

(cc) "Publication-related Biomedical Materials." Tangible research material of biomedical relevance first produced in the course of CIRM-Funded Research including but not limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data), as described in a published scientific paper as provided by Title 17, California Code of Regulations, section 100603. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs. This term does not include tangible research material of biomedical relevance that is commercially available, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

Rationale:

To make specific the language and terminology used in formulating these regulations.

SECTION 100602 – INVENTION AND LICENSING REPORTING REQUIREMENTS.

Purpose:

This section carries forward existing invention and licensing reporting requirements from sections 100302 and 100402.

To ensure efficient use of CIRM-funded inventions, grantees are required annually to notify the CIRM of certain progress invention-related activities. This section identifies the information pertinent to such activities that must be reported in addition to any other information required by the CIRM under other regulations.

Subdivision (a) states a Grantee must have written agreements with named third parties requirement prompt disclosure to the Grantee of any CIRM-Funded Invention or Technology.

Subdivision (b) carries forward from section 100302 language setting a timeline for Grantee notification to CIRM when an inventor discloses a CIRM-funded Invention to the Grantee.

Subdivision (c) carries forward from section 100402, subdivisions (a) through (f) and section 100302, subdivisions (c) through (e). These sections describe the timing and content of reports to the CIRM regarding patent and patent applications and all Licensing Activities, assignments, Exclusive Licenses, Non-Exclusive Licenses and Material Transfer Agreements relating to CIRM-Funded Inventions and Technologies.

Subdivision (d) carries forward the existing confidentiality provision from section 100402, subdivision (a).

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) To fulfill this role, the CIRM must monitor the work of grantees and ensure that inventions are pursued and exploited wherever possible. Therefore, this regulation is necessary to ensure that the CIRM is kept apprised whenever inventions are made and the steps taken or not taken regarding patents of those inventions. In addition, the reporting of licensing agreements ensures that the CIRM is able to determine whether CIRM-funded inventions are being used appropriately in the search for therapies and cures.

SECTION 100603. PUBLICATION REQUIREMENTS.

Purpose:

This section carries forward almost verbatim existing publication requirements from section 100403.

This section identifies the procedures and content for publication of CIRM-supported research results. This section requires submission of copies of the publication to the

CIRM, identification of where the MTA or similar document may be found, and a sample acknowledgment of CIRM funding.

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) The CIRM also supports broad sharing of intellectual property of all kinds and encourages the timely publication of scientific articles in open-access journals that provide immediate access to scientific accomplishments by the scientific community and general public. It is the CIRM's intention to create a database for tracking CIRM-funded inventions, patent applications and license agreements that involve CIRM-funded patented inventions based on information received from grantee organizations. Non-confidential information about CIRM-funded intellectual property may be shared with the public through a CIRM annual report. As a result, this regulation is necessary to ensure CIRM is aware of CIRM-supported research results that the grantee deems worthy of publishing. The advance press release requirement also ensures the CIRM is kept abreast of and can report important progress of CIRM-supported research.

Subdivisions (a) through (c) ensure the CIRM can support sharing of research findings with the scientific community and the general public as a whole through the creation of a repository for such findings. This resource is intended to allow access by the scientific community and the general public to summaries of published scientific articles resulting from CIRM-funded projects. The regulation supports this disclosure by requiring abstracts to be written by the authors of scientific articles specifically for the general public and submitted to the CIRM within 60 days of the publication of the corresponding scientific articles.

SECTION 100604. PUBLICATION-RELATED BIOMEDICAL MATERIALS.

Purpose:

This carries forward the concept of sharing biomedical materials that are described in a publication as embodied in both of the existing regulations (100304 and 100404) governing non- and for-profit organizations. The proposed regulation carries forward almost verbatim existing regulation 100404, which describes in greater detail than section 100304 the circumstances under which CIRM may approve alternatives to the sharing requirement.

This section requires grantees to share biomedical materials described in published scientific articles for research purposes within a certain time after a receipt of a request unless legally prohibited from doing so. The section provides for CIRM-approved deviation in some circumstances and provides that authors may provide requestors with

information on how to reconstruct or obtain the material. The section requires materials to be shared without cost or at cost.

Rationale:

It is expected that intellectual property of all types will be created as a consequence of CIRM grants, loans and contracts. This regulation is intended to provide recipients of CIRM funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with CIRM funds and is designed to assist recipients in complying with their obligations under the Bayh-Dole Act and CIRM funding policy. In order to achieve maximum public benefit, data and biomedical materials (including research tools) should be as freely available as possible in the public domain.

SECTION 100605. PATENT APPLICATIONS:

Purpose:

This section carries forward existing policy as contained in sections 100305 and 100405 relating to patents. The new regulation also adds language in subdivision (b) pertaining to arrangements Grantees must have in place with third parties to ensure compliance with CIRM regulations.

Subdivision (a) emphasizes that except for the rights of March-In retained by the State, nothing in the regulations grants CIRM an ownership interest in CIRM-Funded Research or Technology.

Subdivision (b) states Grantees may retain or transfer all or a portion of any of Grantee's right, title or interest to any CIRM-Funded Invention or CIRM-Funded Technology and to any patent or patent application relating thereto. Notwithstanding the foregoing, transfer of all or any portion of said right, title or interest must be made subject to provisions and obligations of these Regulations. Grantees must ensure that all arrangements entered with Grantee Personnel and Collaborators, and all transfers of all or any portion of right, title, or interest concerning CIRM-Funded Research, CIRM-Funded Inventions or CIRM-Funded Technology comply with these Regulations.

Subdivision (c) carries forward existing section 100405 and subdivision (a) of section 100305 pertaining to costs of patent prosecution.

Subdivision (d) carries forward existing subdivision (a) of section 100305 clarifying that Grantees may recover costs from third parties through license fees or other consideration.

Rationale:

It is not a policy of the CIRM to fund costs associate with patent applications. This regulation is necessary to ensure grantees are aware of conditions of their award. The

new regulation takes existing concepts in sections 100305 and 100405 and adds clarifying language to emphasize Grantee ownership of IP and to describe the responsibility Grantees have to ensure third parties are aware of their obligations under the regulations.

SECTION 100606. LICENSING CIRM-FUNDED PATENTED INVENTIONS:

Purpose:

This section carries forward existing responsibilities embodied in section 100406 and also 100306.

Subdivision (a) states that except as provided in Title 17, California Code of Regulations, section 100610, nothing in these Regulations grants CIRM an ownership interest in CIRM-Funded Research or CIRM-Funded Technology.

Subdivision (b) states that if a Grantee elects not to develop a CIRM-Funded Invention or CIRM-Funded Technology itself, then it shall make reasonable efforts to negotiate Non-Exclusive Licenses for third party development of such CIRM-Funded Inventions or CIRM-Funded Technology, unless doing so would put the Grantee at a competitive disadvantage with a competitor or the materials are already shared or otherwise publicly available..

Subdivision (c) states that a Grantee may negotiate an Exclusive License for CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention and describes the items that must be documented with an Exclusive License.

Subdivision (d) carries forward the provisions of subdivision (c)(4) of section 100406 and subdivision (d) of section 100306.

Subdivision (e) carries forward provisions of subdivision (a) of section 100406 and subdivisions (a) and (g) of section 100306.

Subdivision (f) is an **optional** subdivision that carries forward a distinction for Non-Profit Grantees from subdivision (a) of section 100306.

Subdivisions (g) and (h) carry forward existing provisions in subdivisions (c)(5) and (c)(6) of section 100406 and subdivisions (g) and (h) of section 100306.

Rationale:

Due to the importance of effective patent licensing to the development and availability of new products arising from CIRM-funded inventions, the CIRM licensing policy includes several important elements such as appropriate use of non-exclusive and exclusive

licenses, diligent efforts to commercialize CIRM-funded inventions and plans for access to resultant therapies and diagnostics for qualified patients in California.

For inventions with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners.

Awardee organizations are responsible for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress. Awardee organizations are required elsewhere to submit a licensing activities report for CIRM-funded patentable inventions on an annual basis.

CIRM seeks to ensure development of each invention for the broadest possible applications, optimizing the number of products developed from CIRM-funded inventions. This is accomplished first and foremost through diligent assertion of inventorship rights to inventions in accordance with current patent law. In addition, CIRM policy is for awardees to retain those ownership rights for transfer to the private sector through licensing instead of assignment. In the due diligence phase of licensing activities, awardee organizations are required to document the development and commercialization capabilities of the intended licensee, and include terms in the license agreement that address all relevant therapeutic and diagnostic indications for which the invention is applicable. This strategy allows CIRM awardees to engage in licensing negotiations which ensure the broadest and most expeditious development of new products.

CIRM encourages the use of non-exclusive licenses and recognizes that exclusive licenses may be required to enable development of therapies. Awardee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies will be purchased in California by public funds the therapies at a discounted price. These access plans may be made available by CIRM for review by the ICOC and the general public on an annual basis.

CIRM seeks to ensure that licensees of CIRM-funded patented inventions obtain the appropriate scope of rights necessary for them to develop potential applications of the invention while optimizing public good through the widespread use of the invention.

SECTION 100607. ACCESS REQUIREMENTS.

Purpose:

This section carries forward existing provisions in section 100407. Section 100407 further develops concepts initially addressed in section 100307.

Subdivision (c) contains language that is additional to existing section 100406 that states that Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that their proposed access plan satisfies the requirements of this Section.

Subdivision (d) elaborates on existing section 100407 by stating that CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

Rationale:

As a consequence of expenditure of the "first dollar" of CIRM funding, the for-profit awardee organization agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. The access plan shall be consistent with industry standards extant at the time of commercialization. This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California's taxpayers.

In addition, the awardees will provide the therapies at a discount price to residents whose therapies are purchased in California by public funds. For drugs generated as a consequence of CIRM funding, awardees agree to provide drugs at benchmarks described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) to eligible Californians under that program. Awardees also agree to provide discount pricing for therapies in addition to drugs that result from CIRM funding.

SECTION 100608. REVENUE SHARING

Purpose:

This section carries forward virtually verbatim existing provisions in section 100408 and the concepts embodied in section 100308. The last sentence of subdivision (b)(3) is added to address the timeline for the end of the revenue sharing obligations when the revenue is derived from unpatented CIRM-Funded Inventions or Technology.

Rationale: The additional language is necessary to address the broader scope of the regulations and incorporation of the new terms "CIRM-Funded Inventions" and "CIRM-Funded Technology."

SECTION 100609. PRESS RELEASE REQUIREMENTS

This section carries forward existing language of section 100409.

Rationale: The simpler language of section 100409 is carried forward in lieu of section 100309, which contained additional language relating to CIRM participation in press releases that is deemed no longer necessary.

SECTION 100410. MARCH-IN RIGHTS

Purpose:

This section carries forward virtually unchanged the existing provisions of section 100410 and large parts of section 100310. Two important changes are proposed:

Subdivision (b) no longer contains a provision for march-in for failure to satisfy requirements for public use, as provided in existing subdivision (b)(3) of section 100410 and subdivision (a)(3) of section 100310.

Subdivision (e) now contains a timeline for the appeal process described in that subdivision. The section states that within thirty (30) days of the date CIRM issues a March-In Notice, the subject Grantee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing of its intent to appeal CIRM's decision. Within sixty (60) days of the March –In Notice date, the subject Grantee must submit a written statement of the reasons for the appeal and any supporting materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the ICOC shall render a final determination on the appeal within one hundred twenty (120) days of the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless and until the ICOC renders a final determination on the appeal. The ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.

Rationale:

The proposed changes to existing regulations are intended to eliminate a potentially confusing march-in ground ("public use") whose equivalent in federal law has no concomitant basis in state law or practice; and to further elaborate on the timelines for a Grantee that wishes to avail itself of the appeal process described in the regulation.

SECTION 100611 – ASSURANCE OF THIRD-PARTY COMPLIANCE

Purpose:

This section is a new section not previously explicitly the subject of its own regulation.

This section states that a Grantee shall take affirmative steps to document and ensure compliance with applicable CIRM regulations by Grantee Personnel, Collaborators, licensees and other transferees of right, title or interest any CIRM-Funded Invention or CIRM-Funded Technology, CIRM-Funded Research. Grantee agrees to provide documentation establishing compliance by third-parties at CIRM's request. In the event

a Grantee fails to provide CIRM with adequate documentation to establish third-party compliance, CIRM may require Grantee to perform an audit of the third-parties and compel their compliance at the Grantee's expense.

Rationale:

The proposed section is intended to ensure that Grantees have in place the mechanisms necessary to establish compliance of third parties with the requirements of CIRM's regulations. This regulation enables the CIRM to track Grantee performance and the performance of third parties with obligations under the regulations.

************END************